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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,327	05/09/2001	Robert J. Levy	047172-0170	2799

110 7590 08/22/2003

DANN, DORFMAN, HERRELL & SKILLMAN  
1601 MARKET STREET  
SUITE 2400  
PHILADELPHIA, PA 19103-2307

[REDACTED] EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
1632	15

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/851,327	LEVY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Scott D. Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 24 June 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-6,10,11,13,17,19,20,22-25,27-31 and 33-39 is/are pending in the application.
- 4a) Of the above claim(s) 2,6,10,11,13,17,19,20,22-25 and 29-31 is/are withdrawn from consideration.
- 5) Claim(s) 27,28,33,35 and 36 is/are allowed.
- 6) Claim(s) 1,3-5,34 and 37-39 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6) Other: \_\_\_\_\_

## **DETAILED ACTION**

The amendment filed 6/24/03 has been entered. Claims 7-9, 12, 14-16, 18, 21, 26 and 32 have been cancelled. Claims 1, 3-5, 27, 28, and 33 have been amended. Claims 34-39 have been added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

Claims 2, 6, 10, 11, 13, 17, 19, 20, 22-25, and 29-31 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9, filed 10/25/02.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior

nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

***Claim Rejections - 35 USC § 112***

Claims 34 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 34 recites that the cell is a vascular smooth muscle cell. Applicant indicates that pages 16 or 18 provide support for this claim *inter alia*. However, there is no mention of vascular smooth muscle cells on these pages, much less a description of using the claimed composition to enhance transfection of such cells. The only place in the specification mentioning vascular smooth muscle cell (page 24, lines 1-4) is a discussion of the function of tenascin C produced in vascular smooth muscle cells, and does not describe using tenascin C or any other of the “agents” to enhance transfection of vascular smooth muscle cells. Thus, the originally filed specification fails to support the embodiment of the invention now being claimed, which is new matter.

Claim 37 is directed to a composition comprising “a carrier that permits controlled release of” tenascin C. Applicant indicates that pages 16 or 18 provide support for this claim *inter alia*. However, page 16 describes a much narrower embodiment where the composition

Art Unit: 1632

comprises “*a polymeric carrier such as a controlled release film or nanoparticle or microparticle*” (emphasis added). Applicant has presented no evidence that controlled release carriers other than polymeric films, nanoparticles or microparticles were contemplated at the time the application was filed. Thus the claim incorporates new matter.

Claims 1 and 3-5 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action of 12/18/02 because the specification, while being enabling for enhancing transfection of cultured cells with cationic liposomes comprising plasmid by growth in the presence of tenascin C before, during, or after transfection, does not reasonably provide enablement for any other embodiments embraced by these claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record set forth in the Office action of 12/18/02 as applied to claims 1, 3-5, 7-9, 12, 14-16, 18, 21, and 26. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The compositions of these claims include limitations which are taught in the specification as being for *in vivo* use.

Applicant's arguments filed 6/24/03 have been fully considered but they are not persuasive. Applicant has amended claims 1 and 3-5 limiting the agent to tenascin C, and asserts that this is sufficient to overcome the rejection. Applicant has not addressed the whole rejection,

which indicated that the nucleic acid component be a plasmid in a cationic liposome, and that the specification enables only enhancing transfection of cultured cells with the composition. The Office has provided a *prima facie* case that the specification does not enable the full scope of the claimed invention. Applicant has provided no arguments pertaining to the remaining issues raised in the rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on 703 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Scott D. Priebe  
Primary Examiner  
Art Unit 1632